

Remarks

I. Status of the Claims and Application

The above-captioned application represents U.S. national phase of international application PCT/SE97/00566. At the time of entry into the United States, the application had a total of 18 claims. In a Preliminary Amendment filed on May 21, 1998, claims 13-16 were deleted and claims 3-5, 8-10, 12, 17 and 18 were amended.


Two responses to Office Actions have been filed prior to the present response. On December 18, 1998, a response was filed in which claims 1, 5-7, 8, 12 and 17 were amended. After having received a second Office Action dated February 12, 1999, Applicants filed a request for a continued prosecution application and also submitted a response. In this, minor amendments were made in claims 7, 10 and 12.

In the present response, Applicants have introduced further amendments to claim 17. Claim 18 was canceled and replaced with new claims 19 and 20. In addition, claims 21 and 22 have been introduced. Thus, the claims now pending in the application are 1-12, 17 and 19-22.

II. The Amendments

Claim 17 was amended to indicate that the claimed method involves applying an anesthetic composition to the periodontal pocket of a patient. This amendment was suggested by the examiner on pages 2 and 3 of the Office Action and support may be found in the specification on page 12, lines 9-10.

Claim 18 was broken up into two claims, 19 and 20. The first of these is directed to a process for making compositions containing more than one surfactant and the second, claim 20 is directed to a process of making a composition when there is only one surfactant present. These amendments were introduced in response to the allegation on page 3 of the Office Action that claim 18 is not clear, in part, because of confusion regarding how the process will be carried out when only one surfactant is present. Support for most of the steps of claims 19 and 20 can be found in original claim 18. In addition, both claims 19 and 20 recite that the pH of compositions



is adjusted so that it is greater than or equal to $pK_a - 1$ wherein pK_a is the lowest pK_a of the anesthetics used in the composition. Support for this amendment may be found on page 5 of the specification, lines 17-21.

New claim 21 recites specific ranges for local anesthetics and surfactants. Support for the presence of 0.5 to 20% of local anesthetic can be found on page 3, lines 26-28. Support for the use of up to 50% of surfactant may be found on page 5, lines 12-13. Claim 22 modifies claim 21 by defining the pH of the composition. Support for this amendment may be found on page 5 of the specification, lines 17-21.

None of the amendments introduce new matter into the application and their entry is therefore respectfully requested.

The Rejections

I. Rejection of Claims Under 35 U.S.C. § 112, First Paragraph

On page 2 of the Office Action, the examiner rejects claims 1-12 and 17-18 under the first paragraph of 35 U.S.C. § 112 alleging that the specification does not enable the concentrations of surfactant present in the claims. In addition, the examiner cites prior art references as disclosing certain aspects of the claimed compositions. The Office Action also states:

Applicants' argument that the compositions of the invention tend to use an amount of surfactant that is either outside the range of the prior art or at the extreme lower end is not persuasive. Page 5 of the specification discloses that the total amount of surfactant(s) is preferably present in an amount up to 50% by weight.

Additionally, the specification discloses only an oil-in-water emulsion or microemulsion and it is not seen that a water-in-oil emulsion is contemplated.

Applicants respectfully traverse this rejection.

First, it should be noted that, in terms of enablement, the references cited by the examiner are not relevant. Enablement is concerned solely with the issue of whether one of skill in the art can make and use a claimed invention based upon the information provided in the specification. In the present case, the only skill that is required is the ability to mix together local anesthetics, surfactants and water. Clearly, this should not raise an issue with regard to enablement regardless of the concentration of surfactant used.

It appears from the cited references that the examiner may be attempting to reject claims based upon a lack of novelty, *i.e.*, under 35 U.S.C. § 102. As set forth in Applicants' previous response, none of the references cited disclose a composition in the form of an emulsion or a microemulsion. Therefore, a novelty rejection, if in fact that is what is intended by the examiner, cannot be sustained. Compositions may be legitimately distinguished from one another based upon their physical form, *e.g.*, gel versus liquid. The previous argument that the examiner refers to in the present Office Action, *i.e.*, referring to the amount of surfactant present, was not intended to, itself, serve as a basis for distinguishing the prior art (in particular U.S. 5,635,540). Instead, Applicants were attempting to suggest a possible reason as to why the compositions disclosed in the reference are not in the physical form of the compositions claimed (*i.e.*, why they are not in the form of an emulsion or microemulsion).

With respect to the allegation that the specification only discloses an oil-in-water emulsion, it is respectfully submitted that the form that an emulsion takes is an inherent property of the relative amounts of oil and water present. As such, the property need not be separately recited as a claim limitation. Nevertheless, the examiner is correct insofar as, under the conditions set forth in the specification, it is an oil-in-water emulsion that will be formed. Although Applicants do not believe that it is absolutely necessary, they will consider alternative language specifying an oil-in-water emulsion if the examiner so desires.

II. Rejection of Claims Under 35 U.S.C. §§ 112, Second Paragraph

On pages 2 and 3 of the Office Action, the examiner rejects claims 1-12 and 17-18 under 35 U.S.C. § 112, second paragraph. There are three basic arguments that are set forth. First, it

is alleged that the term "oil form" is unclear since the term "oil phase" is used on page 6 of the specification. In response, Applicants submit that the term "oil form" is supported in many places in the specification, including the claims as originally filed and, *inter alia*, page 3, line 8 and page 7, line 2. The term is self-explanatory – it means that local anesthetic is added to preparations as an oil as opposed, for example, to being added as a dry salt. The term "oil phase" refers to the evenly dispersed oil particles that are part of an emulsion or microemulsion. It should be emphasized, however, that, as indicated on page 6, lines 16-18, that there are not separate phases in the sense of there being separate layers of water and oil.

The examiner also alleges that the term "wherein at least one surfactant has thermoreversible gelling properties" is unclear in cases where a composition has only one surfactant. Again, Applicants respectfully submit that this term is self-explanatory and can have only one meaning. Specifically, if there is only one surfactant present, it must have thermoreversible gelling properties. If there are several surfactants, then at least one of them must have thermoreversible gelling properties. Although Applicants do not believe that the claim terminology is unclear, they will be happy to consider a reasonable alternative suggested by the examiner.

At the bottom of page 2, it is alleged that claim 17 is confusing because the word "administering" suggests that preparations are given orally or parenterally. The examiner suggests language indicating that compositions are applied to the periodontal pocket of a patient. In response, Applicants have amended claim 17 to incorporate the language suggested by the examiner. It is therefore submitted that this basis of rejection has been obviated.

On page 3 of the Office Action, it is alleged that claim 18 is unclear for several reasons. First, it encompasses preparations containing both single and multiple surfactants and it is alleged that the claim does not properly apply to both types of preparations. The terms "slowly" and "suitable" are objected to and it is alleged that the claim is unclear because the pH and final weight of solutions are not stated. In response, Applicants have canceled claim 18 and replaced it with two other claims, 19 and 20. The latter are separately directed to preparations containing

multiple surfactants (claim 19) and preparations having only one surfactant (claim 20). The terms "slowly" and "suitable" have been eliminated from claims and a definition has been provided for the pH of compositions. A specific weight has not been recited because this will vary from preparation to preparation. The final weight of preparations is not of critical importance to the recited method and can be varied depending upon the specific needs of the person preparing the composition. Thus, the absence of a specific number does not render claims indefinite.

In light of the above considerations, Applicants submit that none of the claims presently pending in the application contain language which renders them indefinite under 35 U.S.C. § 112, second paragraph. It is therefore respectfully requested that the examiner's rejection of claims under this section be withdrawn.

III. Rejection of Claims Under 35 U.S.C. §§ 102 and 103

On pages 3 and 4 of the Office Action, the examiner rejects claim 1 as being anticipated by FR 2,704,429 and Nyqvist-Mayer, *et al.* (*J. Pharm. Sci.* 75:365-373 (1986)). These same two references are used to reject claims under 35 U.S.C. § 103. The Office Action alleges that:

The references disclose the pharmaceutical emulsion of claim 1. The remaining claims differ over the references in requiring specific limitations, method of preparation and method of use. However, it will be obvious to one of ordinary skill in the art to use the specific limitation, method of preparation and method of use because once the composition is known, it would be within the skill of the artisan to optimize the composition with the particulars. Additionally, it would be obvious to use a topical anesthetic composition to anesthetize a periodontal cavity, since the disclosed topical anesthetics are well known in the art for dental use. Furthermore, no unobviousness is seen in the method of preparation, since each of the recited steps is conventional in the art.

Applicants respectfully traverse these rejections.

In order to be anticipatory, a single reference must disclose all of the elements of a claimed invention. In the present case, it does not appear that either of the references cited by the

examiner disclose the use of a surfactant with thermoreversible gelling properties (required by paragraph ii of claim 1) or a final composition having thermoreversible gelling properties such that the composition is less viscous at room temperature than after introduction onto a mucous membrane of a patient (as required in paragraph iii of claim 1). Unless the examiner can point to specific teachings regarding these limitations, it is respectfully submitted that a rejection on novelty grounds cannot be validly maintained.

Moreover, Applicants submit that there is nothing in the cited references that would make the use of a thermoreversible surfactant or thermoreversible composition obvious. For example, there are no teachings to suggest that the non-thermoreversible surfactants and compositions disclosed in the references are inadequate or that it would be desirable to make the gel state of preparations dependent upon their introduction into the oral cavity. Thus, Applicants can see no valid basis for maintaining the rejection of claims on obviousness grounds. Unless the examiner can point to a secondary reference teaching thermoreversible polymers and a suggestion in the cited references that the teachings therein be combined to arrive at the claimed compositions, it is respectfully submitted that the rejection of claims on novelty and obviousness grounds should be withdrawn.

Conclusion

Applicants submit that all of the rejections under 35 U.S.C. §§ 112, first and second paragraphs, 102, and 103 have been overcome by the amendments and remarks made herein. It is therefore respectfully requested that these rejections be withdrawn and that the presently pending claims be allowed.

If, in the opinion of the examiner, a phone call may help to expedite prosecution of the above-captioned application, the examiner is invited to call Applicants' undersigned attorney at (202) 639-6585.

Respectfully submitted,

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